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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/427,657 10/26/99 ALITALO

K 28967/35061A

MARSHALL O'TOOLE GERSTEIN
MURRAY & BORUN
6300 SEARS TOWER
233 SOUTH WACKER DRIVE
CHICAGO IL 60606-6402

HM12/1025

EXAMINER

SORBELL, E

ART UNIT	PAPER NUMBER
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1633

DATE MAILED:

10/25/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/427,657

Applicant(s)

ALITALO ET AL.

Examiner

Eleanor Sorbello

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 April 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8, 10-18 and 21-72 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 10-18 and 21-72 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 8 6) ☐ Other:

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Response to amendm nt

1. The Examiner and Art Unit location of your application in the PTO has changed.

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Examiner Eleanor Sorbello, Group Art Unit 1633.

2. Applicant's amendment and response to the official Office Action mailed November 14, 2000 as Paper No. 9, has been received and filed on April 19, 2001 as Paper No. 11. Claims 1, 10, 18, 21, 22, 26-29 have been amended, claims 9, 10, 19, 20 have been canceled, and claims 31-72 have been added. **Claims 1-8, 10-18, 21-72 are pending.** Applicant's amendments and arguments have been thoroughly reviewed, but are not persuasive for the reasons that follow. Any rejections not reiterated in this action have been withdrawn as being obviated by the amendment of the claims and/or applicant's argument.

3. Applicant's arguments are addressed below on a per section basis.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

5. Claim 29 is rejected under 35 U.S.C. 102(b) as being anticipated by Alitalo (W/O 97/05250).

Alitalo taught nucleotide sequences encoding VEGF-C.

The claims are directed to kits which essentially are nucleotide sequences or vectors encoding the polypeptide VEGF-C. Labels and instructions do not contribute any essential patentable feature to the invention.

Therefore the claim is rejected as being anticipated by Alitalo.

6. Claim 29 is rejected under 35 U.S.C. 102(a) as being anticipated by Achen (W/O 98/07832).

Achen taught nucleotide sequences encoding VEGF-D.

The claims are directed to kits which essentially are nucleotide sequences or vectors encoding the polypeptide VEGF-D. Labels and instructions do not contribute any essential patentable feature to the invention.

Therefore the claim is rejected as being anticipated by Achen.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 1-6, 10-18, 22-32, 49-58, 63-69, 71, 72 are rejected under 35

U.S.C. 103(a) as being unpatentable over Isner (U. S Pat. No: 5,652,225 and 5,830,879) in view of Alitalo (W/O 97/05250).

Isner (U.S. pat. No. 5,652, 225) teach delivery of a nucleic acid encoding an angiogenic protein in cationic liposomes and adenoviral vectors. (See abstract). Isner also teaches that a method of inducing formation of new blood vessels in a tissue of a human host comprises contacting an arterial cell or blood vessel via a balloon catheter. They teach that one such angiogenic protein is a VEGF protein. They did not teach VEGF-C or VEGF-D specifically.

Isner (U.S. pat. No. 5,830,879) teach methods of inducing reendothelialization of the lining of a blood vessel of an injured blood vessel comprising administering a nucleotide encoding a VEGF protein. They teach that the resulting reendothelialization of the injured blood vessel inhibits smooth muscle cell proliferation and consequently reduces restenosis. In this patent the intended use of using the VEGF may not be directly to inhibit of reduce stenosis, but the end result is the same.

Isner et al. did not specifically teach VEGF-C as an anigogenic protein for the formation of new blood vessels or for the inhibition of stenosis or restenosis. However, at the time of filing of the instant application Alitalo et al. had taught that VEGF-C may be an inducer of angiogenesis of blood and lymphatic vessels, and in the formation of collateral vessels around arterial stenosis and into injured tissues after infarction. (See

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page 30 paragraph 1). Therefore, it was known at the time of filing of the instant application that VEGF-C had the same function as the VEGF of Isner in the stimulation of blood vessel formation, and therefore for the inhibition of stenosis or restenosis and therefore a suitable alternative to VEGF.

Therefore, Isner and Alitalo taught all limitations of the claims which are therefore rejected.

9. Claims 21-51, 57-69, 71-72 are rejected under 35 U.S.C. 103(a) as being unpatentable over Isner (U. S Pat. No: 5,652,225 and 5,830,879) in view of Achen et al.(WO 98/07832).

Isner et al. teach methods as discussed above.

Isner et al. did not however, teach methods that incorporated VEGF-D.

However, Achen et al. teach that VEGF-D is another member of the VEGF family and have described VEGF-D as being the most closely related VEGF member to VEGF-C. (See abstract). Achen et al also teach a DNA fragment encoding the portion of the human VEGF-D polypeptide from residues 93-201 as the functional peptide. (See page 550, col. 2). Achen also teach that the receptor binding functions of VEGF-C and VEGF-D are similar. (See page 553, col. 1, paragraph 2). Achen et al. teach VEGF-D stimulates endothelial cell proliferation and angiogenesis. (See abstract).

Therefore, because VEGF-D stimulates angiogenesis and it was known at the time as taught by Isner that any VEGF will function to inhibit restenosis, it would have

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been obvious at the time the invention was filed to include VEGF-D in limitations of the claims and a possible alternative to VEGF.

Therefore, Isner and Achen taught all limitations of the claims as discussed herein.

10. Claims 1-6, 10-18, 22-72 are rejected under 35 U.S.C. 103(a) as being unpatentable over **either** Isner in view of Alitalo as applied to claims 1-6, 10-18 above, **or** Isner in view of Achen as applied to claims 21, 33-48 **and** further in view of Martin et al (WO 98/20027, Published 14 May, 1998).

Isner, Alitaloa and Achen teach methods, and kits as discussed above. Therefore, it would have been obvious to include both VEGF-C and VEGF-D in claims of the instant invention as it was known at the time the invention was filed that VEGF-C and VEGF-D have similar functions. It also would have been obvious to include further limitations such as the active peptide of VEGF-D as being that between residues 93-201.

Isner et al. did not teach a collar that fits around the blood vessel.

Martin describes a delivery device (See claim 12, page 65) for delivery of therapeutic compositions to blood vessels comprising a collar which fits around a blood vessel at or near the site of hyperplasia to be treated or prevented.

Therefore, one of ordinary skill in the art would have been motivated to include the limitations as set forth in the instant invention which are rejected for being obvious.

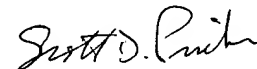
Conclusion

11. Claims 1-6, 10-18, 21-72 are rejected for the reasons set forth above.
12. Claims 7, 8 are objected to for depending on rejected claims.
13. Any inquiry concerning this communication should be directed to Eleanor Sorbello, who can be reached at (703)-308-6043. The examiner can normally be reached on Mondays-Fridays from 6.30 a.m. to 3.00 p.m. EST.

Questions of formal matters can be directed to the patent analyst, Tracey Johnson, whose telephone number is (703) 305-2982.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Clark, can be reached on (703) 305-4051. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

If the claims are amended canceled and/or added the applicants are required to follow Amendment Practice under 37 CFR § 1.121 (<http://www.uspto.gov>) and A CLEAN COPY OF ALL PENDING CLAIMS IS REQUESTED to facilitate further examination.



SCOTT D. PRIEBE, PH.D
PRIMARY EXAMINER